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HFI-35 7/31/97 purged

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 29 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Paul D. Chapman
President and CEO
Chattanooga Group, Inc.
4717 Adams Road
P.O. Box 489
Hixson, Tennessee 37343-0489

Dear Mr. Chapman:

We have reviewed the labeling and promotional material you submitted to this office on March 11, 1997. This review revealed that your firm is distributing the Forte Clinical Protocol System (CPS) Series (Ultrasound, 200/P, 200 Stim, 200 Combo, 400 Stim, and 400 Combo), and other powered muscle stimulators, ultrasound diathermy, inferential current therapy and TENS units. These products are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Forte Clinical Protocol System (CPS) Series, the Forte CB450, and the Forte ES450 are misbranded within the meaning of section 502(o) in that a notice or other information was not submitted, as required by section 510(k). A search of the FDA database revealed that while your firm has submitted several 510(k)s for ultrasound diathermy and electrical muscle stimulators, none have been submitted for devices with these names or any device that includes the CPS system. These devices require a 510(k), irrespective of any other change they may incorporate, because they include the CPS System which is a change in design which could significantly affect safety or effectiveness.

The CPS Series and the following devices: Intelect Legend Ultrasound, Intelect Legend Stim, and Intelect HVP are also misbranded within the meaning of section 502(o). Our records reveal that 510(k)s have not been submitted for devices with these names, or any devices for wound healing. These devices require a 510(k) irrespective of any other change they may incorporate because they are labeled for wound healing, which is a major change in intended use.

The CPS Series, the Forte CB450, the Forte ES450, and all of the above devices are adulterated within the meaning of section 501(f)(1)(B) in that they are Class III devices under section 513(f) and do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

The Intelect Legend is further adulterated and misbranded within the meaning of section 501(f)(1)(B) and 502(o) in that the labeling for the device includes claims for edema reduction, wound healing, trigger point applications, wound care, tennis elbow, AC joint, TMJ, and a number of non-thermal effects including stimulation of tissue regeneration, soft tissue and bone repair, changes in cell metabolism, and promotion of pain relief. Also, please be advised that non-thermal diathermy devices are currently regulated as Class III devices.

Also, please be advised that any representation that creates the impression of official approval of a device or its waveform because of complying with the premarket notification regulations is misleading and constitutes misbranding; and that any representation that a PMA is in effect is prohibited. Therefore, the phrase "It has been approved to market by the FDA.", referring to Chattanooga Hydrogel in the brochure "Wound Care Site Seller", and any other statements which may imply FDA approval of any of your devices must be deleted.

Failure to promptly correct these violations can result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. You should notify this office in writing within fifteen (15) working days from the date you received this letter of the specific steps you have taken to correct the noted violations including an explanation of each step taken to prevent the recurrence of similar violations. You should also provide a detailed comparison of your previously cleared and your currently marketed powered muscle stimulators, ultrasound diathermy, inferential current therapy and TENS devices including specifications, features, and intended use, and any and all changes in design, material, components, performance, or intended use. You should also identify the clearances you have obtained for the MediPads and MediGel transdermal drug (hydrocortisone and lidocane) delivering system and for use of your devices for iontophoresis and phonophoresis, generally. Also, identify the clearances you have obtained for the Chattanooga Hydrogel. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please direct your response to:

Edgardo Santiago, Chief
Orthopedic, Physical Medicine & Neurology Devices Branch, HFZ-343
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

This letter is not intended to be an all-inclusive list of deficiencies with your products. It is your responsibility to assure adherence to each requirement of the Act and regulations. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (800)638-2041 or by fax at (301)443-8818 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Debra A. Clingan at (301)594-4654.

Sincerely yours,

Gladys Rodriguez for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health